CHLORASEPTIC SORE THROAT CITRUS- phenol spray CHLORASEPTIC SORE THROAT CHERRY- phenol spray CHLORASEPTIC SORE THROAT MENTHOL- phenol spray Prestige Brands Holdings, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Chloraseptic Spray

Drug Facts

Active ingredient

Phenol 1.4%

Purpose

Oral Anesthetic/Analgesic

Uses

For the temporary relief of occasional minor irritation, pain, sore mouth and sore throat.

Warnings

Sore Throat Warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor or dentist if

- sore mouth symptoms do not improve in 7 days
- irritation, pain or redness persists or worsens
- swelling, rash or fever develops

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

In case of overdose or accidental poisoning, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 3 years of age and older:

- Apply to the affected area (one spray).
- Allow to remain in place for at least 15 seconds, then spit out.

• Use every 2 hours or as directed by a doctor or dentist. **Children under 12 years of age** should be supervised in the use of this product. **Children under 3 years of age:** consult a doctor or dentist.

Other information

- store at room temperature
- check expiration date before using.

Inactive ingredients

Citric acid, FD&C Red #40, FD&C Yellow #6, flavor, glycerin, purified water, sodium saccharin, sodium citrate

Questions?

1-800-552-7932 Chloraseptic.com

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Inactive ingredients

FD&C red no. 40, flavors, glycerin, purified water, sodium chloride, sodium citrate, sodium saccharin, sucralose

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Other information

- store at room temperature
- check expiration date before using

Inactive ingredients

D&C green no. 5, D&C yellow no. 10, FD&C green no. 3, flavor, glycerin, purified water, sodium saccharin, sucralose

Questions?

1-800-552-7932 Chloraseptic.com

PRINCIPAL DISPLAY PANEL

Chloraseptic® Phenol/Oral Anesthetic

SOOTHING CITRUS | 6 FL OZ (177 mL)



PRINCIPAL DISPLAY PANEL

Chloraseptic® Phenol/Oral Anesthetic

CHERRY Flavor

6 FL OZ (177 mL)



PRINCIPAL DISPLAY PANEL

Chloraseptic® Phenol/Oral Anesthetic

MENTHOL Flavor | 6 FL OZ (177 mL)



PRINCIPAL DISPLAY PANEL

Chloraseptic® Phenol/Oral Anesthetic

CHERRY Flavor

0.67 FL OZ (20 mL)



CHLORASEPTIC SORE THROAT CITRUS

phenol spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67172-112	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PHENOL (UNII: 339 NCG44TV) (PHENOL - UNII:339 NCG44TV)	PHENOL	3.5 mg in 0.7 mL		

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			

GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics			
Color	ORANGE	Score	
Shape		Size	
Flavor	CITRUS	Imprint Code	
Contains			

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:67172-112- 31	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2010		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part356	09/01/2010		

CHLORASEPTIC SORE THROAT CHERRY

phenol spray

Product Information					
Product Type HUMAN OTC DRUG Item Code (Source) NDC:67172-111					
Route of Administration	ORAL				

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENOL (UNII: 339 NCG44TV) (PHENOL - UNII:339 NCG44TV)	PHENOL	3.5 mg in 0.7 mL	

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
WATER (UNII: 059QF0KO0R)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

Product Characteristics				
Color	RED	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:67172-111- 31	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2010			
2	NDC:67172-111- 20	1 in 1 CARTON	09/01/2010			
2		20 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	09/01/2010	

CHLORASEPTIC SORE THROAT MENTHOL

phenol spray

Product Information	oduct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67172-113	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENOL (UNII: 339 NCG44TV) (PHENOL - UNII:339 NCG44TV)	PHENOL	3.5 mg in 0.7 mL	

Inactive Ingredients			
Ingredient Name	Strength		
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
WATER (UNII: 059QF0KO0R)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

Product Characteristics			
Color	GREEN	Score	
Shape		Size	
Flavor	MENTHOL	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67172-113- 31	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	09/01/2010	

Labeler - Prestige Brands Holdings, Inc. (159655021)

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